04/04/24 BIG PHARMA

'We're Open for Business': FDA's Peter Marks Says Agency Ready to Review Novel Cancer Vaccines Despite Unknowns + More

The Defender's Big Pharma Watch delivers the latest headlines related to pharmaceutical companies and their products, including vaccines, drugs, and medical devices and treatments. The views expressed in the below excerpts from other news sources do not necessarily reflect the views of The Defender. Our goal is to provide readers with breaking news that affects human health and the environment.

By The Defender Staff

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'We're Open for Business': FDA's Peter Marks Says Agency Ready to Review Novel Cancer Vaccines Despite Unknowns

Fierce Biotech reported:

> As new cancer vaccines — led by Moderna and Merck's mRNA-4157 — near pivotal trial readouts, the FDA's vaccines czar Peter Marks, M.D., Ph.D., said the agency is ready to review the shots despite AI-related unknowns. "We are ready to review — we're open for business," Marks, director of the FDA's Center for Biologics Evaluation and Research, said of cancer vaccines at the 2024 World Vaccine Congress (WVC).
>
> The FDA has approved a cancer vaccine before, namely, Dendreon's

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prostate cancer shot Provenge. Although the next wave of therapeutic cancer vaccines aims to prove efficacy through familiar clinical endpoints — such as tumor progression and overall survival — the novelty of their tech raises new regulatory questions. And neither the FDA nor the biopharma industry seem to have the full set of answers right now.

For Moderna and Merck's mRNA candidate mRNA-4157, though, AI dictates how the individualized vaccine should be formulated to attack cancer. All of this raises a new regulatory question: How much change to the AI algorithm is allowed before the vaccine should be considered a completely new product?

"We don't know," Kyle Holen, Moderna's head of development of therapeutics and oncology, said. "Nobody knows. We're in, like, no-man's land here, because no one's ever done this."

Sanofi to Settle 4,000 Zantac Cancer Lawsuits in U.S. State Courts

Reuters reported:

Sanofi (SASY.PA) has reached an agreement in principle to settle 4,000 U.S. lawsuits linking the discontinued heartburn drug Zantac to cancer, the company said on Wednesday.

Sanofi did not disclose the financial terms of the deal. The agreement, which still needs to be finalized, will resolve most of the lawsuits against the French pharmaceutical company in U.S. state courts, with the exception of Delaware where the majority of the cases are pending. Sanofi did not admit any liability in the settlement and said it is settling to avoid the expense and ongoing distraction of the litigation.

Sanofi still faces about 20,000 lawsuits over Zantac in Delaware state court. A judge in Delaware Superior Court in Wilmington is weighing the fate of about 70,000 cases filed against Sanofi and other defendants, including GSK (GSK.L), Pfizer (PFE.N) and Boehringer Ingelheim.

Plaintiffs and defendants are awaiting a ruling from the judge on whether there is sufficient scientific evidence to support plaintiffs' claims that Zantac causes cancer. The drugmakers notched a significant win in 2022 when another judge dismissed about 50,000 lawsuits making similar claims that had been consolidated in federal court in Florida.

Bird Flu: 'We Are All Over It,' CDC Director Says — a Dip in Routine Vaccinations and a Rise in Measles Cases Also Are on the Agency's Radar

MedPage Today reported:

Although the risk to humans is very low, the case of the Texas farmworker apparently contracting pathogenic avian influenza A (H5N1) from a cow illustrates the importance of data collection, CDC Director Mandy Cohen, MD, MPH, said Tuesday.

Cohen's remarks about the "bird flu" came toward the end of a keynote speech about vaccines' role in preventing disease, in which she also discussed her concerns about "steps backward" in routine childhood vaccinations. She stressed that the CDC has been focused on and invested in ways to protect the nation and the world from avian flu for 20 years.

The person thought to be infected with highly pathogenic avian influenza A (HPAI) was exposed to dairy cattle in Texas and later reported "eye redness (consistent with conjunctivitis)" as the sole symptom. The patient was treated with "an antiviral drug for flu," told to isolate, and is currently

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recovering, according to a CDC press release.

Beyond avian influenza, Cohen also discussed how the U.S. is "losing some ground" in routine vaccinations of children during her keynote speech. "Whether that's the measles vaccine, the polio vaccine, the varicella vaccine — we have seen a small decrease," she said — from 94% to 92% — in vaccination rates for children entering kindergarten.

The CDC is trying to turn things around through initiatives like the Routine Immunizations on Schedule for Everyone (RISE) program. However, the problem is a global one. As many as 25 million children worldwide missed routine vaccines during the last 2 to 3 years, Cohen said, and as many as 18 million are "no-dose children."

No, Big Pharma's High Prices Don't Drive Innovation

The Washington Post reported:

> This year, for the first time, a handful of prescription drug manufacturers will negotiate with the Centers for Medicare and Medicaid Services over how much taxpayers will pay for their costly drugs. Big pharmaceutical companies have long argued that such price negotiations will lower their profits, reducing their ability to innovate. But is that true?
>
> Not according to an analysis we published at our think tank, the Foundation for Research on Equal Opportunity. Our research shows that the biggest drug companies largely fail to turn their enormous profits into discoveries. Instead, most innovation is taking place at small, unprofitable start-ups, whose drugs are largely excluded from Medicare's new price negotiation system. When it comes to pharmaceutical innovation, smaller is better.
>
> You'd think that the biggest drug companies with the biggest R&D budgets would have the most productive research labs. But it doesn't work that way.
>
> If large companies' labs are so unproductive, you might ask, why are so many of the world's top-selling drugs manufactured by bigger companies? Because of the FDA's high regulatory costs. Smaller companies can't always afford to conduct the large billion-dollar clinical trials required for approval. As a result, big companies treat emerging start-ups like their farm team, buying off their best drugs, raising their prices and reaping the profits.

Don't Count Us out yet, Novavax Says

Axios reported:

> After losing out on the COVID-19 vaccine race, Novavax is hoping its experimental combo flu-COVID vaccine can help turn around its fortunes. But it finds itself in a familiar position of playing catch-up.
>
> Why it matters: A year after it warned about its ability to remain in business, the Maryland company is trailing Pfizer-BioNTech and Moderna in the development of a combination product that would reduce the need for multiple shots during respiratory virus season.
>
> Driving the news: Pfizer and Moderna have Phase 3 trials well underway for their combo products, and Novavax plans to start its late-stage trial this fall. If successful, it's planning for a 2026 launch.
>
> Between the lines: Unlike the mRNA-based platforms Pfizer and Moderna use, Novavax's protein-based shot relies on technology that's been in use for much longer. The company sees that as a selling point for some who are more comfortable with older technology, though there's still been relatively little takeup of its COVID shot.

Can 23andMe Reinvent Itself as a Drug Discovery Company?

Financial Times reported:

> Nowadays, it has become ridiculously cheap and easy to discover your own DNA. Spit into a tube, post it to a lab and a genetics testing company will email you the results for as little as $99. The collapse in the cost of this technology is staggering, outstripping the exponential advances in computing power, known as Moore's Law. At the beginning of the century, it cost more than $95mn to sequence one human-sized genome.
>
> This data revolution has enabled millions of people to trace their ancestry and discover lost relatives. It has also helped doctors diagnose genetic diseases and created an astonishing research resource for scientists. While researchers have been salivating about this informational treasure trove, investors seem less impressed. But intriguingly, several billionaires have laid contrarian bets that 23andMe, one of the biggest testing companies, can reinvent itself as a valuable drug discovery business. Can it succeed?
>
> With foresight, 23andMe created a therapeutics research division nine years ago to exploit its extraordinary cache of genetic data. Its database now includes 15 million users of whom 80% have consented to share their anonymised data for research. The company has been working with the pharmaceutical giant GSK, focusing on immuno-oncology drugs. "We are like a telescope that can see 10 times further into the biological universe," Jennifer Low, head of therapeutics development at 23andMe, tells me.

Moderna Shares Fall After Judge Sides With Arbutus in Patent Fight

Reuters reported:

> Shares of Moderna (MRNA.O) fell 4% on Wednesday after a U.S. judge issued an order that strengthened Arbutus' arguments in a patent infringement lawsuit related to Moderna's blockbuster COVID-19 vaccines.
>
> Roivant's (ROIV.O) shares gained 4% in afternoon trading, while its subsidiary Arbutus rose more than 17%. In a so-called "claim construction order," U.S. District Judge Mitchell Goldberg interpreted parts of the patents in ways that strengthened Arbutus' case, rejecting Moderna's proposed definitions.
>
> The lawsuit, which was filed in 2022, has Arbutus seeking damages for infringement of U.S. patents related to Moderna's COVID-19 vaccine.
>
> Arbutus said it developed the so-called lipid nanoparticles that enclose the vaccine's mRNA payload, the patents related to which were licensed to Genevant Sciences, a joint venture between Arbutus and Roivant Sciences Ltd.
>
> A trial in the case is currently set to begin next April.

Early Data From Rare-Disease Trial Put Spotlight on Moderna's Efforts to Turn mRNA Into Medicines

STAT News reported:

> Moderna may be best known for its COVID-19 vaccine, but since its start, it's always been set on developing therapies.

It's run into some hurdles as it's pioneered turning mRNA — the strand of genetic material that's at the heart of Moderna's approach — into medicines. But the company's vision of making cells into their own drug factories is showing signs of progress.

On Wednesday, scientists reported interim results from an early study of Moderna's most advanced rare-disease therapy, a treatment for propionic acidemia, a metabolic condition in which the body makes defective versions of enzymes that are required to break down fats and proteins. While the study primarily focused on safety and testing different doses, some patients — most of the participants were children — saw a reduction in the life-threatening metabolic emergencies that can crop up with the disease.

U.S. FDA Approves Basilea Pharmaceutica's Antibiotic

Reuters reported:

The U.S. health regulator approved Basilea Pharmaceutica's (BSLN.S) antibiotic for bacterial infections including multidrug-resistant strains, the FDA said on Wednesday.

The Switzerland-based company was seeking approval of its antibiotic ceftobiprole for the treatment of three conditions – Staphylococcus aureus bacteremia (SAB), acute bacterial skin and skin structure infections, and community-acquired bacterial pneumonia.

The approval expands options for patients who may have developed a resistance to currently available antibiotics. More than 2.8 million antimicrobial-resistant infections occur each year in the U.S., according to government data.

The U.S. market for the intravenous antibiotic, which will be sold under the brand name Zevtera, is projected to be $5.50 billion and is probably going to be the "lion's share of the market for this drug", said Soo Romanoff, an analyst at Edison Group.

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Wendy

20 days ago

Bird flu? Hah! I had it in the early 70s and recovered without the use of any drug, not even any pain killers and there was pain. So I am immune. Also, I note not one mention is made of Vitamin D. Most Americans are deficient in Vitamin D. This is not surprising since most of us never or hardly ever get in the sun. I supplement to make up the shortfall. If all adults maintained a robust level of Vitamin D, there might even be no flu or colds or covid ever again. This is based on actual scientific studies. Well over 100 and counting.

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mcwinaz

20 days ago

Bird Flu: "We are 'all over' it" says CDC Director. Funny, that's how most people feel today about all vaccines - "We are all 'over it' ".

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